Remarks

This is intended to be a complete response to the official action mailed October 15, 2002 in which claims 6, 8, 13, 17, 18, 26-29, 32, 33, 37 and 38 were rejected and claims 1-3, 14, 16, 19, 30, 31, 34-36 and 39 were allowed in a final action.

Applicant respectfully requests entry of the amendments made herein under 37 CFR §1.116 in view of the fact that said amendments cause the rejections to be overcome, and in view of the fact that the amendments have been made in accordance with the examiner's suggestions.

First Rejection Under § 112 ¶2

Claims 17 and 18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the rejection it is stated:

> "Claims 17 and 18 recite the limitation "the detection reagent" in lines 1 and 3 respectively. There is insufficient antecedent basis for this limitation in the claim."

Claims 17 and 18 have been amended to replace "reagent" with "agent", which has antecedent basis in claim 16, which claims 17 and 18 depend from.

In view of the amendments to claims 17 and 18, applicant respectfully requests reconsideration and withdrawal of the rejection under §112 ¶2.

Second Rejection Under §112 ¶2

Claims 6, 8, 26-29, 32-33, 37 and 38 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the rejection it is stated:

> "Claims 32 and 33 (and claims 37 and 38) recite the limitation "the detection reagent" in lines 1 and 3 respectively. There is insufficient antecedent basis for this limitation in the claim."

Claims 32, 33, 37 and 38 have been amended in a manner similar to the amendments of claims 17 and 18. In view of the amendments, applicant respectfully requests reconsideration and withdrawal of the rejection.

In the rejection it was also stated:

> "Claims 6 and 8 (and claims 26 and 27, 28 and 29) are unclear in the recitation of "amplified DNA" in lines 15 and 2 respectively, because it is unclear what "amplified DNA" is being referred to. For example, does the term refer to "forming an amplified DNA" in line 9 of claim 6, or to other amplified DNA? This rejection can be easily overcome by reciting instead "said amplified DNA" in lines 15 and 2 of claims 6 and 8 (26 and 27, 28 and 29) respectively."

Claims 6, 8 and 26-29 have been amended in accordance with the examiner's suggestion to further identify the secondly recited "amplified DNA" as "said amplified DNA" to correct the antecedent basis of the term.

In view of the above, applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under §112 ¶2.

Rejection Under §102(b)

Claim 13 stands rejected under 35 U.S.C. 102(b) as being anticipated by Atlas et al. (US Patent 5,298,392; 3/29/194).

In the rejection it is stated:

> "Absent a precise definition as to what is meant by "specifically detecting E. Coli", the recitation has been broadly interpreted to encompass "particularly or especially the detection of E. Coli", which is taught by Atlas et al. As the claim does not recite definite bacterial species that would not be detected by the method, the recitation of "specifically detecting E. Coli" or "specific for E. Coli" in instantly pending claim 13 is not sufficient to distinguish the method of claim 13 over the teachings of Atlas et al. It is noted that this rejection can be overcome by amending the claim to explicitly recite "specifically detecting E. Coli but not *Shigella boydii, Shigella flexneri, Salmonella typhi, Salmonella enterica, Salmonella arizonae, Enterobacter cloacae, Enterobacter aeromonas, Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Pseudomonas* species, *Aeromonas hydrophila, Acinetobacter* species, *Klebsiella pneumoniae, Listeria monocytogenes, Neisseria meningitidis, Campylobacter jejuni, Campylobacter coli, Erwinia* species, and *Citrobacter freundii* (as recited on pages 19 and 20 of the specification)."

Claim 13 has been amended in accordance with the examiner's suggestion to indicate that the method detects E. coli but not *Shigella boydii, Shigella flexneri, Salmonella typhi, Salmonella enterica, Salmonella arizonae, Enterobacter cloacae, Enterobacter aeromonas, Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Pseudomonas* species, *Aeromonas hydrophila, Acinetobacter* species, *Klebsiella pneumoniae, Listeria monocytogenes, Neisseria meningitidis, Campylobacter jejuni, Campylobacter coli, Erwinia* species, and *Citrobacter freundii* . The amendment is supported on pages 19-20 of the specification.

In view of the above, applicant respectfully submits the claim is now allowable over the cited art and respectfully requests reconsideration and withdrawal of the rejection under §102(b) over Atlas et al.

Priority

In the official action it was stated:

> "The response traverses the examiner's indication that SEQ ID NOS 2, 3, 15, and 16 are not due the benefit of the priority date of the provisional application 60/149,365 (August 13, 1999) on the grounds that the statement at page 23, lines 7-11, of the '365 application" "primer pair is selected from the group consisting of primer sequences comprising a substantial part of SEQ ID No 1 and SEQ ID NO 2..." supports SEQ ID NOS 2, 3, 15, and 16 of the instant application because SEQ ID NOS 2 and 3, and SEQ ID NOS 15, and 16 comprise a "substantial part" of SEQ ID NO 1 (identical in '365 and the instant application)

> and SEQ ID NO 2 (identical to SEQ ID NO 14 in the instant application) respectively. This argument has been thoroughly reviewed but was not found persuasive because sequences *consisting* of the specific nucleotide sequences of SEQ ID NO 2, 3, 15, and 16 were not disclosed in the provisional application, nor did the provisional application make clear what constituted a "substantial part" of SEQ ID NOS 1 and 2."

Although the issue of priority of SEQ ID NOS 2, 3, 15, and 16 does not presently bear on the allowability of the pending claims, applicant continues to traverse examiner's assertion that said sequences are not due the benefit of the priority date of the provisional application. The issue of priority rests on the meaning and interpretation of "substantial".

The courts have, on numerous occasions, addressed the use and meaning of the terms "substantial" or "substantially".

For example, in *York Products, Inc. V. Central Tractor Farm & Family*, 99 F.3d 1568, 1572-1573, 40 USPQ2d 1619 (U.S.C.A. Fed. Cir. 1996) (provided herein as Attachment 1), the court held that "substantially" ordinarily meant "considerable in...extent," (quoting *American Heritage Dictionary Second College Edition* 1213 (2d ed. 1982)), or "largely but not wholly that which is specified," (quoting Webster's Ninth New Collegiate Dictionary 1176 (9th ed. 1983).

Moreover, in *Ecolab*, the Court of Appeals for the Federal Circuit referred to *Andrew Corp. V. Gabriel Elecs. Inc.*, 847 F.2d 819, 821-822, 6 USPQ2d 2010, 1013 (Fed Cir. 1988) (provided herein as Attachment 2) in stating:

that terms such as "approach each other," "close to," "substantially equal," and "closely approximate" are ubiquitously used in patent claims and that such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claims subject matter from the prior art, have been accepted in patent examination and upheld by the courts.

If one follows the reasoning of the Federal Circuit in York Products, i.e., the "substantial" means "largely but not wholly that which is specified", one would then reasonably conclude that a "substantial part" of SEQ ID NO 1 or SEQ ID NO 2 [now SEQ ID NO 14] would be a "large but not whole" part of SEQ ID NO 1 or SEQ ID NO 2 [now SEQ ID NO 14].

It can be readily seen from Table V and from the Sequence Listing of the present specification that present SEQ ID NOS 2 and 3 each comprise 23 of the 24 nucleotides of SEQ ID NO 1. Likewise SEQ ID NOS 15 and 16 each comprise 23 of the 24 nucleotides of SEQ ID NO 14.

Given the definition of "substantial" sanctioned by the Federal Circuit ("largely but not wholly that which is specified"), it is evident that SEQ ID NOS 2 and 3 are "substantial parts" of SEQ ID NO 1, and SEQ ID NOS 15 and 16 are

"substantial parts" of SEQ ID NO 14, regardless of whether or not they are explicitly described in the provisional application. They are inherently described in the provisional application as "substantial parts" of the entire 24-base sequence.

Applicant therefore respectfully submits SEQ ID NOS 2, 3, 15 and 16 are therefore due the benefit of the priority date of the provisional application, U.S. Serial No. 60/149,365.

Conclusion

In view of the above, applicant respectfully submits the claims are in a condition for allowance and requests issuance of a Notice of Allowance therefore.

Marked Up Version of the Claims

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Respectfully submitted,

Christopher W. Corbett, Ph.D.
Reg. No. 36,109
DUNLAP, CODDING & ROGERS, P.C.
P.O. Box 16370
Oklahoma City, OK 73113
Customer No.: 30589
Telephone: (405) 478-5344
Facsimile: (405) 478-5349
Agent for Applicant

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

6. (Twice Amended) A method of specifically detecting E. coli in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

treating the DNA sample under PCR conditions with a primer set specific for E. coli for forming an amplified DNA wherein the primer set comprises SEQ ID NO:1 and SEQ ID NO:14; and

detecting the presence of **said** amplified DNA as an indication of the presence of E. coli in the liquid or liquified sample.

8. (Twice Amended) The method of claim 6 wherein in the step of detecting the presence of **said** amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

13. (Three-times Amended) A method of specifically detecting E. coli **but not *Shigella boydii, Shigella flexneri, Salmonella typhi, Salmonella enterica, Salmonella arizonae, Enterobacter cloacae, Enterobacter***

aeromonas, Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Pseudomonas* species, *Aeromonas hydrophila, Acinetobacter* species, *Klebsiella pneumoniae, Listeria monocytogenes, Neisseria meningitidis, Campylobacter jejuni, Campylobacter coli, Erwinia* species, and *Citrobacter freundii in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

selecting a target gene of E. coli and selecting an E. coli-specific target DNA sequence in the target gene;

incubating the DNA sample under amplification conditions with a DNA polymerase and a primer pair specific for E. coli **but not *Shigella boydii, Shigella flexneri, Salmonella typhi, Salmonella enterica, Salmonella arizonae, Enterobacter cloacae, Enterobacter aeromonas, Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Pseudomonas* species, *Aeromonas hydrophila, Acinetobacter* species, *Klebsiella pneumoniae, Listeria monocytogenes, Neisseria meningitidis, Campylobacter jejuni, Campylobacter***

coli, Erwinia* species, and *Citrobacter freundii for amplifying the target DNA sequence; and

detecting the presence of amplified DNA as a specific indication of the presence of E. coli carrying the selected E. coli-specific target DNA sequence, wherein the target gene is the *lamB* gene of *Escherichia coli*.

17. (Twice Amended) The kit of claim 16 wherein the detection **[reagent] agent** is a dsDNA stain.

18. (Twice Amended) The kit of claim 16 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection **[reagent] agent**.

26. (Once Amended) A method of specifically detecting E. coli in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

treating the DNA sample under PCR conditions with a primer set specific for E. coli for forming an amplified DNA wherein the

primer set comprises SEQ ID NO:2 and SEQ ID NO:15; and

detecting the presence of **said** amplified DNA as an indication of the presence of E. coli in the liquid or liquified sample.

27. (Once Amended) The method of claim 26 wherein in the step of detecting the presence of **said** amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

28. (Once Amended) A method of specifically detecting E. coli in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

treating the DNA sample under PCR conditions with a primer set specific for E. coli forming an amplified DNA wherein the primer set comprises SEQ ID No:3 and SEQ ID NO:16; and

detecting the presence of **said** amplified DNA as an indication of the presence of E. coli in the liquid or liquified sample.

29. (Once Amended) The method of claim 28 wherein in the step of detecting the presence of **said** amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

32. (Once Amended) The kit of claim 31 wherein the detection **[reagent] agent** is a dsDNA stain.

33. (Once Amended) The kit of claim 31 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection **[reagent] agent**.

37. (Once Amended) The kit of claim 36 wherein the detection **[reagent] agent** is a dsDNA stain.

38. (Once Amended) The kit of claim 36 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection **[reagent] agent**.